1 In the Bull's-Eye

On a February morning, snow is falling lightly outside Kathy Maglione's fifth-grade classroom in the blue-collar town of Linden, New Jersey, some 10 miles south of Newark. Gianna, Amanda, and Raquel are in close consultation at a table near the back, huddled over a clear plastic funnel and some coffee filters, screen filters, disposable cups, and plastic bags. They are variously pouring gravel, salt, and diatomaceous earth—earth containing the ground-up remains of tiny aquatic organisms—into cups of water; then, they'll try to separate the ingredients again by pouring the mixtures through some kind of filter.

"I don't think the sodium chloride will go through this."

"Well, I don't want to use a coffee filter. The powder will go through it."

"Are you serious? This is grounded-up bones?"

"We're touching people's bones here?"

"The salt won't go through. It's too thick."

"It's not people's bones, it's animals."

Two months later and 30 miles away, on an unusually chilly late-April afternoon, a fleet of blue buses ferries several hundred shareholders across the wooded, dandelion-strewn sprawl of Raritan Valley Community College to the 2002 annual meeting of Merck & Co., Inc.

The mood in the purple and burgundy college auditorium is amiable and polite. Most of the questions to Raymond V. Gilmartin, the company's chairman, president, and chief executive officer, are on the order of, Why is my pharmacist always out of Timoptic eyedrops? or, Are you doing any research into obesity? The officially nominated directors are all approved; the unofficial shareholder resolutions are all defeated. Everyone nibbles melon slices and chocolate pastries.

The amiability is tinged with resignation, however. The past six months, for people who own pharmaceutical stocks, have been a long parade of bad news. Patents on numerous key products are expiring—five for Merck alone. Earnings at many companies are flat or falling, and even firms with good numbers are seeing their share prices slide. But it's not just the financials that are nagging at the people in the Raritan Valley auditorium. Every day some government official or consumer group in the United States is questioning something the industry does. Even as Gilmartin is fielding the queries on eyedrops and obesity, the chairman of the Federal Trade Commission is complaining to the Senate Committee

on Commerce, Science and Transportation about the way pharmaceutical companies try to keep less expensive generic drugs off the market. Congress is considering an array of measures that challenge the industry from every angle, measures to allow cheaper drugs to be imported from Canada, to make it harder to block generics, to tighten the rules on clinical testing, to put more restrictions on advertising, and—the granddaddy of them all—to add prescription drugs to Medicare coverage, with the potential that would bring for regulating prices. State politicians, too, are pressuring the industry to lower prices by filing lawsuits and demanding discounts for their Medicaid programs.

Worse news—though the retired Merck scientists and secretaries in the purple auditorium don't know it—is yet to come. Within the next three months, there will be regulatory questions about their company's hot new arthritis drug and accounting questions about its Medco subsidiary, and their stock's value will plummet.

A onetime administrative assistant has stock options that will expire at the end of the year. "I might as well throw them out," she jokes bleakly, staring at herself in the ladies' room mirror.

"It's almost like pin-the-tail-on-the-donkey, which pharmaceutical company you buy," shrugs a former temp worker who lives in one of Merck's hometowns.

Sheldon Schwartz worked at Merck for 14 years in the 1950s and 1960s, rising from mailroom to marketing. Now he does industrial lighting, and he's worried about the implications of some of the news stories he's read. Why does one say Merck is going "back" to basic research? Hasn't Merck

been doing research all along? Why doesn't Merck have more blockbuster drugs ready to replace the ones that are about to go off patent?

He's been going to the company's annual meeting for years. But this time, he says, "it's not the same."

Both these scenes are stories of Merck.

The first is the story Merck likes to tell the world—the Merck of the two legendary leaders, George W. Merck and P. Roy Vagelos; the Merck beloved by small investors; the Merck that discovered a treatment for river blindness in Africa and then handed out the drug for free. This Merck develops groundbreaking medications for tuberculosis, high cholesterol, osteoporosis, and AIDS. This Merck is also an upstanding member of the community. It provides child care for its employees. It gives away tens of millions of dollars.

In that fifth-grade classroom, Gianna, Amanda, and Raquel were part of a unique 10-year, $20 million project that Merck launched in 1993 to completely revamp the way science is taught in four New Jersey and Pennsylvania school districts, including the one where Roy Vagelos graduated from high school in 1947. With its own money plus $2.5 million from the National Science Foundation, Merck hired consultants, trained hundreds of teachers, sent some of the teachers out to Arizona and to Washington, D.C., for further training, bought new science materials, helped set up community science fairs to draw in parents, arranged professional evaluation, and essentially rewrote the curriculum for all the districts' elementary and middle school science classes to

emphasize learning by doing rather than learning by textbook reading.

"If it weren't for Merck, this initiative would not have happened," said Dolores Maslo, the tall, elegant, perfectly coiffed director of science for the Linden public school district, as she showed off class after class on that snowy February morning. There was a glimmer of tears in her eyes.

That Merck certainly exists. However, it was the second Merck that looked to be the Merck of the twenty-first century—its labs struggling, its profits slipping, and under attack from politicians, consumers, doctors, other businesses, and insurance companies.

Of course, it was not alone. All the multinational pharmaceutical giants—collectively known as Big Pharma—were facing an overwhelming and unprecedented barrage of scientific, financial, and political problems, much of it their own fault. But that was just the point. Merck was supposed to be different from the rest. If even Merck couldn't come up with good drugs or win the public's love, then the industry really was in trouble.

To understand what was happening to the pharmaceutical industry as the twentieth century moved into the twenty-first, the best place to start is probably with the dollars. Politicians, employers, and patients saw general inflation rising only 3 to 4 percent, overall health care up 5 to 7 percent, health insurance premiums jumping 12 to 14 percent—and spending on prescription drugs soaring almost 20 percent. News stories showed grandmas forced to choose between food and medi-

cine, or elderly couples taking turns filling their prescriptions each month because they couldn't afford two sets of pills. Then, in the same newspapers and magazines, the business pages reported that the pharmaceutical industry was raking in profits of 17 or 18 percent, making it the most profitable industry in the United States. The public connected the dots: *Big Pharma is making obscene profits from the pockets of starving grandmothers . . . .*

Overseas, the headlines were even worse. Millions of impoverished children were suffering from AIDS in Africa and Brazil. Lifesaving medication was available, but incredibly, the drug makers were charging the same $10,000 to $12,000 a year that they billed in the United States. Under the glare of publicity, the companies slashed their prices, to the point where they claimed they were just breaking even. The price cutting didn't do much for their image, however, because they seemed to be dragged kicking and screaming to do it.

Actually, there were plenty of drug companies eager to provide the most popular drugs cheap: generic drug-makers like Barr Laboratories, Inc. and Mylan Laboratories Inc.

The way it was supposed to work, under a 1984 U.S. law governing drug patents, was that the big pharmaceutical companies would do the research, discover the drugs, and get exclusive rights to market the products at their comfortable profit margins for, typically, 20 years. Then, the generic drug makers would get to jump in with copycat versions, selling for one-fifth or less of the patented drug's price. Health insurance plans would include financial incentives to encourage people to use the generics. At that point, the so-called branded

companies would forget all about their old drugs and go discover new ones.

That was all very nice in theory. But when the crunch came—as a rush of blockbusters began to come off their patents like dominoes between 2000 and 2002, including such make-or-break names as the allergy pill Claritin and the antidepressant Prozac—the theory fell apart. Instead of simply kissing good-bye to their steady moneymakers, the industry desperately began looking for new ways to patent the old drugs in order to eke out another 6, 12, or 30 months of exclusive rights and keep the generics off the market. Anything would do: the markings on the pill, the color of the bottle it came in, or the chemical compound it produced in people's livers.

In their defense, the pharmaceutical companies pointed out that groundbreaking new drugs don't grow on trees, or even in too many test tubes. Experts argued about how much it really cost to discover the average new drug. Was it $200 million? $500 million? $800 million? Still, there wasn't much debate that it's a long, hard, expensive slog. Although the industry upped its spending on research by close to 70 percent (after inflation) from 1990 to 2001, the number of new drugs approved by the Food and Drug Administration (FDA) pretty much held constant, at around 30 per year, according to The Boston Consulting Group. In other words, more money did not buy more results.

Again, though, as with AIDS, the industry managed to pull the rug out from under its own defense. A sizable number of the FDA approvals weren't for new cures for cancer or other serious ailments; they were for questionable "improve-

ments" to existing brands or the fifth cholesterol drug of the same type. Instead of focusing their millions of research dollars on cures that were needed, too many drug makers took the easy way out.

The mapping of the human genome was supposed to be the answer to Big Pharma's research problems. Yes, it had given the industry an important new tool, and computer modeling had made research faster and more efficient. But the study of genes was turning out to be even more complex than expected. There are something like 30,000 genes in the human genome, each of which can produce up to a dozen proteins, which in turn may (or may not) catalyze a reaction that will act on a particular disease. It could be 2010 or later before any products from genomics research would be ready for market—by which time a lot more patents would have expired.

And after all that, after struggling through those years of decoding and genomics research, what kind of product would the pharmaceutical labs end up with? Most likely a narrowly targeted niche drug that wouldn't make much money.

All of which meant that, even as the public was howling over obscene profits, the days of 18 percent returns might not be around much longer. For many companies whose hot-selling drugs had lost their patents, those days were already gone.

So if big new products were going to be sparse and the generic drug makers couldn't be blocked, the pharmaceutical industry turned to the other tried-and-true business strategy for pumping up the bottom line: marketing. From time beyond memory, drug companies had wooed doctors with

everything from free samples to doughnuts to hard-to-get theater and sports tickets, hoping the doctors, in return, would prescribe their drugs. Then, in 1997 Big Pharma was handed a magnificent new weapon, thanks to changes in federal rules—TV advertising. The companies poured in a billion dollars, then two, then two and a half. They hired the best of Madison Avenue, who in turn brought in celebrities like Olympics skater Dorothy Hamill and erstwhile presidential nominee Bob Dole. The aim, Big Pharma said, was to "empower" consumers so that they would crack their doctors' omniscience and demand the brand-name medication they saw on TV. Unfortunately for the pharmaceutical world, it's hard to calibrate empowerment.

Pretty soon, people started asking a lot of questions, and the questions weren't necessarily, "Will you prescribe Vioxx for me?" AARP, the powerful lobbying group for seniors, warned that the ads might entice people to demand expensive medicine they didn't really need. Believers in natural health said American society relied too much on pills, anyway. Ethicists worried that there was something wrong about advertising serious medicine as if it were toothpaste. Consumer advocates said that all the money that was going into commercials ought to be used instead to keep prices down. Doctors weren't exactly thrilled to have their opinions challenged (or to waste nonbillable hours arguing with patients). Even the hoary old wining and dining of physicians came under so much attack that the industry's trade group, Pharmaceutical Research and Manufacturers of America (PhRMA), had to produce a code of conduct drastically curtailing all the freebies.

Popular culture was quick to latch onto the newest villain. In 2001, John le Carré came out with a thriller, *The Constant Gardener*, about a rapacious pharmaceutical giant that hides evidence of the fatal side effects of its TB drug and blithely kills anyone who threatens to reveal the truth. Within that same year, two other novels also featured greedy drug companies or overdependence on prescriptions. The hero of the 2000 movie *The Family Man*, in his soulless Wall Street incarnation before he discovers the True Meaning of Life, finds his greatest satisfaction arranging a multibillion dollar drug company merger

To Frank R. Lichtenberg, a professor of economics and finance at Columbia University's Graduate School of Business in New York who specializes in the pharmaceutical industry, the outpouring against the big drug giants wasn't all that surprising. "If their access to pharmaceutical products is limited by price or other reasons, people get upset," he points out. "That's testimony to the pharmaceutical companies' activity and their contribution to society."

And that was exactly the way the companies had always wanted to see themselves—contributing to society. They were the good guys, the purveyors, after all, of something that saves lives and improves health. In his speech in March 2002 to the PhRMA annual meeting, the lobbying group's president, Alan F. Holmer, even dared compare drug makers to the nation's newest heroes, the firefighters who risked their lives when the World Trade Center was attacked on September 11—because drug companies risk millions of dollars researching new cures that may never pay off. Typical

lobbyist hype, of course. But Holmer could be confident he wouldn't be laughed off the podium by his members.

As things degenerated in the winter of 2001–2002, top executives from a big manufacturer brought one of their most vocal critics, Ron Pollack, executive director of a Washington, D.C.–based consumer group called Families USA, to their headquarters to explain what was going on. Pollack, in a backhanded way, actually sympathized with Holmer's point of view. "Here were people seated around the table who thought they were heroes," he later recalled. "They were finding the medicines that were cures for diseases. They thought they were on this great mission. They were profoundly perplexed and hurt that they were being vilified."

How could they be lumped now with the dregs of the business world, with the oil companies and the tobacco industry?

If the pharmaceutical industry was supposedly somehow a little more pure, a little better than the rest of the business world, Merck was the best of the best.

If the scene at the annual meeting could have taken place at almost any other pharmaceutical company, the scene in the fifth-grade classroom was Merck's alone.

Simply put, whether in terms of product or philanthropy, numbers or niceties, no other pharmaceutical company, and perhaps no other U.S. company of any sort, has ever had a reputation like Merck's:

- Number one on *Fortune* magazine's "Most Admired Companies" list for an unprecedented seven years in a row, from 1987 through 1993.
- The only company to stay on *BusinessWeek* magazine's annual ranking of the top 50 performers in the Standard & Poor's 500 index (based on sales growth, earnings growth, total return, and other bottom-line considerations) every year for the first six years running since the list began in 1997.
- The only pharmaceutical company to be included in the bellwether Domini 400 Social Index—a diversified group of 400 companies screened for factors such as product quality, employee relations, community relations, and environmental practices—when the index began in 1990 and for three years afterwards.
- The only pharmaceutical company, as of 2002, to make the National Association for Female Executives' roster of the top 25 companies for executive women each year since the list was launched in 1999.
- A perennial on *Working Mother* magazine's ranking of "100 Best Companies for Working Mothers," qualifying as one of the 10 best for 9 of the list's 16 years.
- The only pharmaceutical company to rate as one of *Fortune*'s "100 Best Companies to Work For" every year since the list started in 1998, and the only pharmaceutical company to qualify for the precursor list, initiated by veteran business writer Milton Moskowitz in 1984, for every year of its existence but one.
- The first pharmaceutical company to win the U.S. Commerce Department's Ron Brown Award for Cor-

porate Leadership, launched in 1997 to honor "companies that have demonstrated a deep commitment to initiatives that empower employees and communities while advancing strategic business interests."

- The only pure-play drug company in that icon of leadership and might, the Dow Jones Industrials.

By the mid-1980s, "Merck was both the Arnold Schwarzenegger and Mother Teresa of American businesses," journalist Barry Werth wrote in *The Billion-Dollar Molecule*, his 1994 book about the founding of a biotech company by a group of ex-Merck scientists.[1]

The double-barreled Merck reputation goes back at least to the 1940s and the discovery of streptomycin. Merck had agreed to provide facilities and staffing to a Rutgers University professor named Selman A. Waksman in return for exclusive marketing rights to any of his results. One of those results was streptomycin—a new, powerful antibiotic that could be used against tuberculosis. The potential market was millions of people, untold millions of dollars; it was like holding the patent on a cure for breast cancer. And Merck, in the public interest, waived its exclusive rights, handing over the patent gold mine to a Rutgers-based foundation.

Through the 1980s and 1990s, the company's research and development prowess was unparalleled in the industry. When Ernst & Young launched an index in 1993 to evaluate R&D spending, revenue, and other financial signposts among the biotechs, the standard it used for comparison was Merck. The company prided itself on creating entire new classes of

treatments, on coming out with revolutionary drugs way ahead of anything else on the market, or even better, on being the only one on the market. It had the first or second significant products for cholesterol, hypertension, osteoporosis, asthma, and a class of pain medications known as COX-2 inhibitors, as well as certain broad-spectrum antibiotics. From the 1960s onward, it produced more breakthrough medicines than any rival. "It means something when someone says, 'We've just hired that R&D person and that person came from Merck.' That carries greater weight than if that person came from wherever," Edward Pittman, the investment analyst specializing in pharmaceuticals for the giant New Jersey public employees' pension fund, asserts. "They are the pharmaceutical company that many in the industry see as the quintessential R&D entity. Merck has become the benchmark for the whole biotech industry," says the chief executive of one of the largest of those biotechs, Don Drakeman of New Jersey–based Medarex, Inc., which genetically engineers mice to carry specific antibodies.

That's not all. *The Merck Manual*—a massive compendium of descriptions and treatments for probably every known human ailment—is a staple of doctors' bookshelves. Merck could boast of never having a drug recalled in the United States (unlike some other pharmaceutical makers it could name). It was the first company to volunteer under the 1983 Orphan Drug Act to manufacture a product that was desperately needed by only a handful of people—the drug industry's version of pro bono work. It was one of the first two companies to sign up with the Council of Institutional

Investors, a shareholder rights organization that investigates corporate management practices, back when "it was a very scary thing for a corporation to do," says Sarah Teslick, the group's executive director. Merck's sales tactics were seen as generally a shade cleaner than everyone else's, its attitude toward generics less hostile. AIDS activists considered it a little more willing to listen. As rivals mixed and matched into giant mergers—some of them more than once—from 1989 to 2000, Merck, virtually alone, held out. It was the biggest, the first, the one to beat.

Every day, staffers in Pfizer Inc's treasury office recorded the high, low, and closing prices of only two stocks, in a book that went back to the 1950s: their own company, and Merck.

And of course, there was Mectizan.

If there's one philanthropic act of Merck's that anyone knows about, it's the donation of Mectizan. Back in the 1970s, when Merck scientists were researching ways to fight parasites in farm animals, they accidentally realized that one of the compounds they were studying, ivermectin, might also be effective against a human disease known as river blindness. Transmitted by common black flies that breed in fast-flowing rivers, the disease causes chronic rashes, itching, and weight loss, as well as blindness. Millions of people in some of the world's poorest countries, mainly in Africa, were infected, with tens of millions more at risk. Up until then there had been no effective treatment. Merck's serendipitous find could have a potential market of over a hundred million people. And virtually none of them could afford to pay for it.

By its own admission, Merck originally hoped that someone else would cover the cost of producing and distributing the drug, which could run tens of millions of dollars annually until the disease was brought under control. The company sought out international health and development agencies, charitable foundations, and local and Western governments. When no one volunteered, there was a debate within Merck as to what to do. To donate Mectizan (as the drug was named) for free would not only eat into profits, but it could also open up the floodgates to demands from other charities for all sorts of freebies. A donation like that would go far beyond what any company had ever done. It's one thing to give away a few runs of an antibiotic that you manufacture anyway, as most drug companies do in some form or another; it's another thing to launch a new line solely for donation, and with no limit on how long you'll keep going or how much money you'll allocate.

But that's exactly what Merck did. On October 21, 1987, Roy Vagelos, then the CEO, declared that Merck would donate "as much Mectizan as necessary, for as long as necessary, to treat river blindness and help bring the disease under control as a public health problem." The company also worked with the World Bank, UNICEF, the World Health Organization, and more than two dozen other groups to set up a distribution system.

One former high-level manager who was in the executive meeting when Vagelos announced his plans still marveled at it years afterwards. "That was an extraordinary day. Roy flatout said to a roomful of senior executives, 'We're going to do

the right thing.' Most of us were thrilled." Ordinary employees called the CEO and wrote him letters saying, "I always thought we were a great company, but I never knew how great until now."

Interestingly, Vagelos, when I asked him why he made the decision to donate the drug, didn't mention the patients suffering from river blindness. He talked about "the people at Merck. The research people and how disappointed they would be if the drug never reached the people that would benefit." Merck was going to discover and produce innovative drugs, even if they were given away. Because great drug companies make drugs.

Of course, Merck has milked its Mectizan reputation for all it's worth. The lobby of its headquarters features a collage of Mectizan-related photos along with a sculpture of a boy leading a blind man—that is, a symbol of the kind of helplessness that Mectizan is supposed to end forever, which has become the program's trademark. "Any time you see someone from Merck, they're telling you that same story about Mectizan," harrumphs Daniel Berman, a Switzerland-based coordinator for the Nobel Peace Prize–winning international relief organization Médecins Sans Frontières (Doctors Without Borders). Nor is the giveaway a pure financial loss, since, as with most donations, the Mectizan program qualifies for tax credits.

Still, it's not every company that even has that sort of reputation to milk. It's not every company that takes as its motto: "We try never to forget that medicine is for the people. It is not for the profits. The profits follow, and if we have

remembered that, they have never failed to appear. The better we have remembered that, the larger they have been."

For a long time, Merck had both, profits and popular acclaim.

But by the early twenty-first century, it wasn't going to be so easy for any pharmaceutical company—even Merck—to have either.